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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,304	04/16/2001	Franz Josef Meyer-Almes	P66378US0	4840

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/762,304	MEYER-ALMES, FRANZ JOSEF	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *30 September 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): none.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 27-41

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). *10/16/03*.

10.☐ Other: _____

LARRY R. HELMS, PH.D
PRIMARY EXAMINER

Misook Yu, 10/18/04

Continuation of 5. does NOT place the application in condition for allowance because:

Claim 38 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicant argues that the specification at page 7 has the support. The specification where applicant points to has a support for "a substrate". However, the specification at page does not have a support for "the fluorogenic substrate". The scope is not the same, thus it is new matter.

Claims 27-41 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and also as failing to comply with the enablement requirement.

Applicant argues that use of non-coumarin-base fluorgenic, DEVD-containing substrates has been disclosed in Liu et al., (1999). However, Liu et al., discloses rhodamine-based flurogenic substrate. However, the instant claims are not limited to the art-known substrate, but still drawn to method of detecting apoptosis by measuring caspase activity by measuring fluorogenic change of a genus of caspase substrate containing DEVD. It appears that aminocoumarin structure connected to DEVD and rhodamine structures connected to DEVD are also important for being fluorogenic. The specification as originally filed does not teach what other structures could be attached to DEVD other than aminocoumarin structure to be a fluorogenic substrate to be used in the claimed screening method. Thus, applicant argument is not commensurate with the scope of the claims. Further, the caspase activity using the rhodamine-based flurogenic substrate in Liu et al., was conducted with purified caspace-3 protein (note Figure 1 at page 3234), but instant claims do not use purified casepase-3 protein. The instant specification does not teach whether the substrate disclosed in Liu et al., could be used in the instantly claimed invention.

Claims 27-41 are also rejected under 35 U.S.C. 102(b) as being anticipated by Martins et al (Dec. 1, 1997, Blood 90, pages 4285-4296). Claims are interpreted as drawn to screening method using aminocouarin-DEVD based assay.

Applicant argues that the instant invention is measuring accumulated caspase activity and the art of record does not teach "measuring the accumulated activity in the sample without previously separating off the cells". This argument has been fully considered not persuasive because instant claims as constructed read on the art. It appears that that the scope of the instantly claimed invention critically dependent upon interpretation of the extent of the scope of "without previously separating off the cells." The Office broadly interprets this limitation as the cells contacted with the substance of is being used (not discarded, i.e. separating off). Applicant argues that cells in the art are washed twice in a serum-free medium i.e., the cells are separated from their original medium. These arguments are fully considered but found unpersuasive because the instant claims do not say anything about the original medium. Thus, this argument is considered as arguing limitation not present in the claims. The body of claims uses the transitional phrase "comprising", which indicates some steps such as washing could be included as long as the cells had not been separated off. Here, at least one aspect of "separating off the cells" could include retaining the substance-contacted cells for caspase activity testing using a fluorogenic substrate. The art teaches teach method of continuously incubating (accumulated caspase activity) the substance without separating off the cells for caspase activity to detect delayed caspace activity, thus anticipating instant claims..

LARRY R. HELMS, PH.D
PRIMARY EXAMINER